

## REMARKS

### **I. STATUS OF THE CLAIMS**

Claims 1, 3, 6, 7, 9, 20, 22, 24, 26-28, 31, 35-37, and 121-123 were pending at the time of the Action. Claim 1 and claim 6 have been amended. Claim 7 has been canceled. Claims 20-22, 24, 26-28, 31, 35, and 36 are withdrawn from consideration at this time. Therefore, claims 1, 3, 6, 9, 37, and 121-123 are currently under examination and presented herein for reconsideration.

### **II. 35 U.S.C. § 112, FIRST PARAGRAPH**

Claims 121-123 are rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement. In particular, it is asserted that the specification or the original claims do not have written description for a mutated vaccinia virus having TK gene mutation in addition to the B18R or B8R genes. Applicants respectfully traverse.

The written description requirement is whether the “description clearly allows persons of ordinary skill in the art to recognize that he or she invented what is claimed.” MPEP 2163.02 (citing *In re Gosteli*, 872 F.2d 1008, 1012, 10 U.S.P.Q.2d 1614, 1618 (Fed. Cir. 1989)).

The specification teaches that vaccinia virus can be engineered as thymidine kinase deficient vaccinia virus, specification at page 26, line 33. One of skill in the art would recognize that based on the teachings of the specification, particularly page 18 that states “It is specifically contemplated that any embodiment discussed with respect to a particular method or composition may be implemented with respect to other methods and compositions of the invention,” that the inventors contemplated all described vaccinia virus can be in a TK minus background. However brief the discussion of thymidine kinase deficient vaccinia virus, the specification supports incorporation of thymidine kinase deficiency into the claimed embodiments. Applicants request reconsideration of the written description rejection of claims 121-123.

### **III. 35 U.S.C. §102 REJECTIONS**

Claims 1, 3, 6, 9, and 37 are rejected as anticipated under 35 U.S.C. §102 by Blanchard et al. (A) or Blanchard et al. (B) or Spehner et al. Claims 1, 3, 6, 9, and 37 are rejected as anticipated under 35 U.S.C. §102 by Feng et al. or Trevor et al. Claims 1, 6, 9, 37, and 121 are rejected as anticipated under 35 U.S.C. §102 by Roberts et al. Applicants traverse.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP § 2131 citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

The current claims are directed to the Copenhagen or Western Reserve strain of vaccinia virus. The cited references do not described a modified Copenhagen or Western Reserve strain of vaccinia virus. All elements of the claimed invention are not described in the cited references and thus do not anticipate the current claims. Applicants respectfully request reconsideration and withdrawal of the rejections.

### **IV. 35 U.S.C. §103 REJECTIONS**

The Action rejects (1) claims 1, 3, 6, 7, 9, 37, 121-123 as being obvious in view of Blanchard et al. (A) and McCart et al., and (2) claims 1, 3, 6, 7, 9, 37, and 121-123 as being obvious in view of Blanchard et al. (A), Roberts et al., and Puhlmann et al. Applicants traverse.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim

limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Claims 1, 3, 6, 7, 9, 37, and 121-123 are not obvious in view of Blanchard et al. (A) and McCart et al. And Claims 1, 3, 6, 7, 9, 37, and 121-123 are not obvious in view of Blanchard et al. (A), Roberts et al., and Puhlmann et al.

Applicants note that the combination of references relied upon do not teach the Copenhagen or Western Reserve strain of vaccinia virus. Therefore, the combination of references does not teach all elements of the claimed invention and does establish a prima facie case of obviousness. Blanchard et al. (A) teach that MVA does not replicate well in most mammalian animal cells (Blanchard et al. (A) abstract). Thus, MVA is an ideal candidate for a vaccine vector and not a good candidate as an oncolytic virus. A stark contrast exists between Copenhagen/Western Reserve and MVA strains of vaccinia virus. The uniqueness of MVA is further detailed in the discussion section of Blanchard et al. (A), see page 1165 left column last paragraph. There is no motivation or suggestion to modify a Copenhagen or Western Reserve strain of vaccinia virus in light of teachings directed to an MVA strain of vaccinia virus. Thus, one of skill would not readily extrapolate characteristics of MVA to Copenhagen strains of vaccinia virus.

Furthermore, as demonstrated in FIG. 2 of the current specification and described on page 84, lines 6-7, the Copenhagen strain demonstrates an unexpected attenuation in normal cells as compared to other vaccinia virus strains. The cited references do not address any expectation in the art that the Copenhagen strain possesses such characteristics, further supporting the non-obviousness of the currently claimed invention.

Applicants respectfully request the reconsideration and withdrawal of the rejections.

**V. DOUBLE PATENTING**

Claims 1, 3, 6, 7, 9, and 37 are provisionally rejected under the doctrine of double patenting over U.S. Pat. App. 11/838,757. Applicants respectfully request this rejection to be held in abeyance until the present application has been allowed.

**VI. CONCLUSION**

The Examiner is invited to contact the undersigned attorney at (512) 536-3167 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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